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10/579,877	05/18/2006	Thomas Dunker	DUNKER ET AL-2 PCT	3786
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COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER MERENE, JAN CHRISTOP L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,877	Applicant(s) DUNKER ET AL.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 7-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 2-5, 7-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9-10,13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites: "piston head is movable along the entire pump body length" and dependent claim 9 recites "a hose bracket sleeve," where it is unclear what the applicant is referring to as the body length, if it is the length measure from tip to tip or a portion of the body. If applicant refers to the body length as being taken from the very ends of body #3, then, as seen in Fig 3, the piston head would not be movable along the "pump body length", where it is also unclear if the applicant is referring to the piston head being movable with the hose bracket sleeve attached or detached. Clarification is requested and the examiner will treat the limitation "pump body length" as any length measured along the body, since the piston head is blocked for movement when the hose bracket sleeve is attached (as seen in Fig 3).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. **Claims 3-5, 7, 14-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz US 3,724,076.

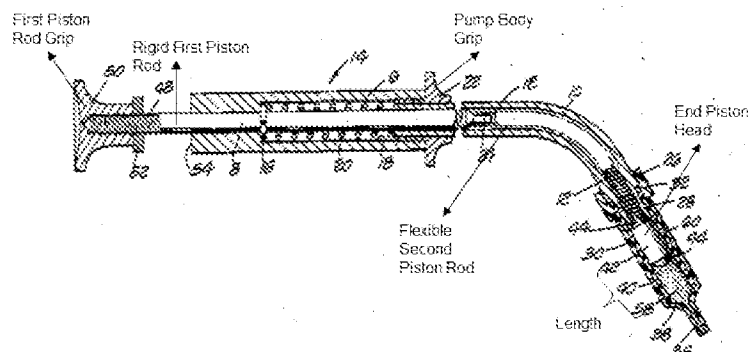
Regarding **Claim 15**, Schmitz discloses an injection pump for application of highly viscous media that have to be applied with pressure during percutaneous vertebroplasty comprising:

(a) a pump body having a pump body proximal end, a pump body distal end, and a pump body length (as seen in Fig below);

(b) a pump body grip fastened at said pump body proximal end (as seen in Fig below); and

(c) a piston system comprising a rigid first piston rod having a first piston rod proximal end and a first piston rod distal end, a flexible second piston rod connected to said first piston rod at said first piston rod distal end and having a second piston rod distal end, a first piston rod grip connected to said first piston rod at said first piston rod proximal end, and an end piston head at the second piston rod distal end for taking up bone cement; wherein said end piston head is movable along the entire pump body length between the pump body distal end and the pump body proximal end (as seen in Fig below where there is a first rigid piston rod connected to a flexible second piston rod and an end piston head moveable along the length).

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Regarding **Claim 3**, Schmitz discloses the pump body comprises a ductile plastic material (see Col 1 lines 65-67).

Regarding **Claim 4**, Schmitz discloses the pump body has a rigidly bent shape (as seen in Fig above and see Col 2 lines 42-44).

Regarding **Claim 5**, Schmitz discloses the flexible second piston rod conforms to the rigidly bent shape of the pump body (as seen in Fig above and Col 2 lines 39-41 where the second piston rod is flexible and can conform to the bent shape).

Regarding **Claim 7**, Schmitz discloses the second piston rod is fitted with a flexible material (see Col 2 lines 39-41).

Regarding **Claim 14**, Schmitz discloses the pump body is arranged at the pump body grip and is firmly rotatable and replaceable (as seen in Fig above in Claim 15 where it is rotatable and replaceable if one chooses to do so).

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5. **Claims 15** are rejected under 35 U.S.C. 102(b) as being anticipated by Clark US 4,801,263.

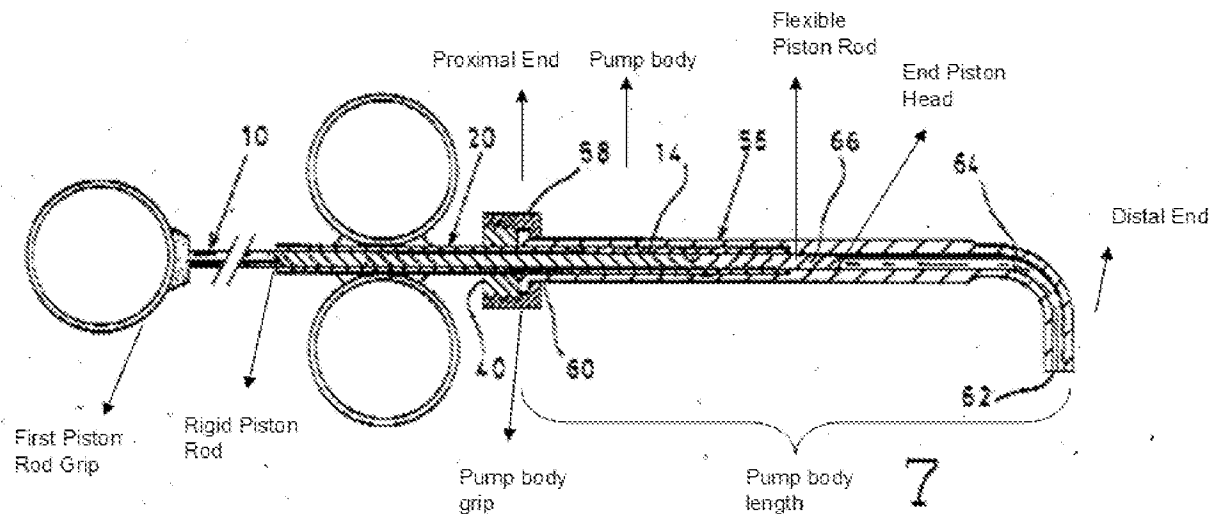
Regarding **Claim 15**, Clark discloses an injection pump for application of highly viscous media that have to be applied with pressure during percutaneous vertebroplasty comprising:

(a) a pump body having a pump body proximal end, a pump body distal end, and a pump body length (as seen in Fig below);

(b) a pump body grip fastened at said pump body proximal end (as seen in Fig below); and

(c) a piston system comprising a rigid first piston rod having a first piston rod proximal end and a first piston rod distal end, a flexible second piston rod connected to said first piston rod at said first piston rod distal end and having a second piston rod distal end, a first piston rod grip connected to said first piston rod at said first piston rod proximal end, and an end piston head at the second piston rod distal end for taking up bone cement; wherein said end piston head is movable along the entire pump body length between the pump body distal end and the pump body proximal end (as seen in Fig below and Col 5 lines 20-30, where there is a first rigid piston rod connected to a flexible second piston rod and an end piston head moveable along the length).

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Regarding **Claim 3**, Clark discloses the pump body comprises a ductile plastic material (see Col 5 lines 20-25).

Regarding **Claim 4**, Clark discloses the pump body has a rigidly bent shape (#64 as seen in Fig above and Col 5 lines 20-30).

Regarding **Claim 5**, Clark discloses the flexible second piston rod conforms to the rigidly bent shape of the pump body (as seen in Fig above in claim 15 and Col 5 lines 20-30).

Regarding **Claim 7**, Clark discloses the second piston rod is fitted with a flexible material (see Col 5 lines 20-25).

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Regarding **Claim 14**, Clark discloses the pump body is arranged at the pump body grip and is firmly rotatable and replaceable (as seen in Fig above in Claim 15 and Fig 4 where the pump rotatable and replaceable if one chooses to do so).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 in view of Fischione US 4,655,749.

Shmitz discloses the claimed invention as discussed above but does not disclose sealing rings.

However Fischione discloses a piston head with sealing rings (#56) which are used to create a suction effect (see Fig 3 and Col 3 lines 40-44, 60-68 and Col 4 lines 38-66, where rings are provided to seal the chamber and prevent leakage, creating a suction effect when the piston #36 is moved up and down).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection pump of Shmitz with the sealing rings in view of Fischione because they prevent leakage of fluid and sealing rings such as O-rings are well known in the art for creating a suction effect within an injection pump device.

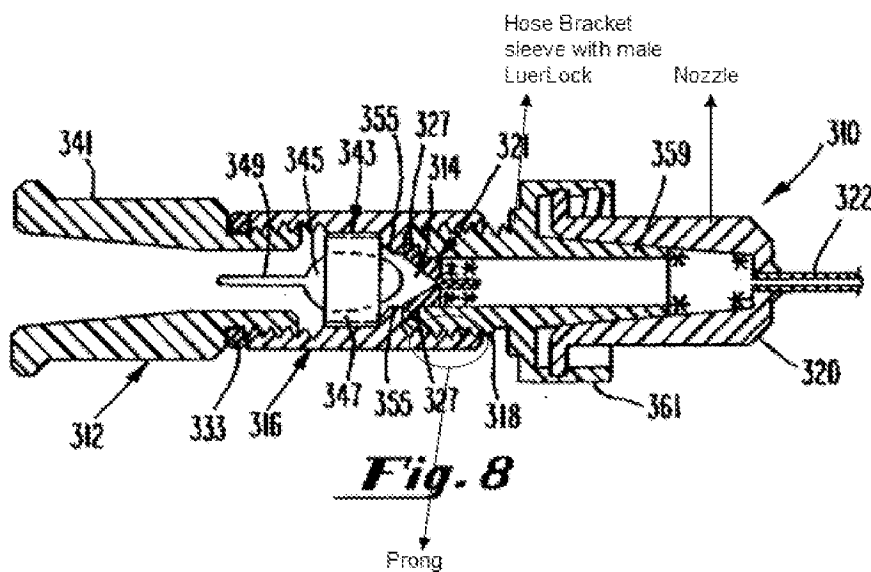
11. **Claims 9-10, 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 in view of Century US 5,513,630.

Shmitz discloses the claimed invention as discussed above, wherein the injection pump has a Luerlock (#36) for attachment with a nozzle (#30 and see Col 2 lines 54-61), but does not specifically disclose a hose bracket sleeve with an attached rotatable male LuerLock at the distal end of the pump body, wherein a nozzle is screwed to the rotatable male LuerLock to take up highly viscous media from a respective vessel which

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nozzle can be unscrewed after absorption of such highly viscous media, wherein the male LuerLock is fitted with a prong to fasten the pump body by radially pressure-forcing the pump body into place.

However, Century discloses disclose a hose bracket sleeve with an attached rotatable male LuerLock at the distal end of the pump body, wherein a nozzle is screwed to the rotatable male LuerLock to take up highly viscous media from a respective vessel which nozzle can be unscrewed after absorption of such highly viscous media, wherein the male LuerLock is fitted with a prong to fasten the pump body by radially pressure-forcing the pump body into place (see figs below and Col 10 lines 59-65, Col 11 lines 4-24, which teaches a standard male LuerLock to connect with a nozzle, where the LuerLock is attached to the body and is rotatable with prongs that help keep the LuerLock in place, which also exerts force on the body).



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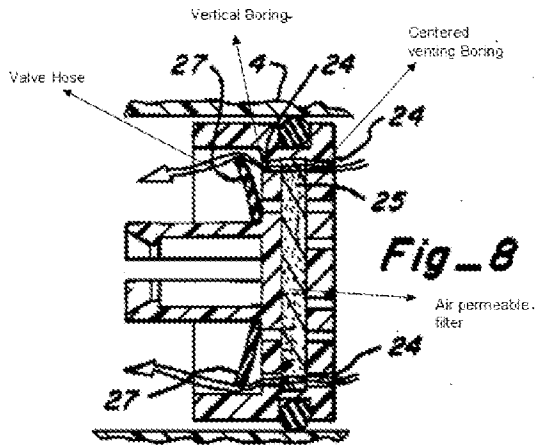
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shmitz with the rotatable male LuerLock connection and prongs in view of Century because it applies a known technique to a known device ready for improvement to yield predictable results of fastening a nozzle against an injection device through radially pressure-forcing to hole the pump body into place.

12. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shmitz US 3,724,076 and Fischione US 4,655,749, as applied to claim 8 above, and in further view of Baldwin et al US 5,238,003.

The combination of Shmitz and Fischione disclose the claimed invention as discussed above but does not specifically disclose the end piston head has a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose.

However, Baldwin discloses a similar injection pump with an end piston head with a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose (as seen in Fig below), where it allows for passage of air but is impervious to fluids (See Col 4 lines 6-18).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Shmitz and Fischione to include the filter and venting boring and valve hose in view of Baidwan as taught above because it allows for passage of air but is impervious to fluids.

13. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark US 4,801,263 in view of Fischione US 4,655,749.

Clark discloses the claimed invention as discussed above but does not disclose sealing rings.

However Fischione discloses a piston head with sealing rings (#56) which are used to create a suction effect (see Fig 3 and Col 3 lines 40-44, 60-68 and Col 4 lines 38-66, where rings are provided to seal the chamber and prevent leakage, creating a suction effect when the piston #36 is moved up and down).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection pump of Clark with the sealing rings in view

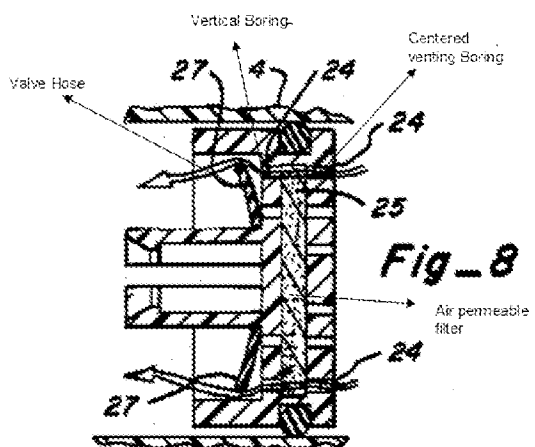
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of Fisschione because they prevent leakage of fluid and sealing rings such as O-rings are well known in the art for creating a suction effect within an injection pump device.

14. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark US 4,801,263 and Fischione US 4,655,749, as applied to claim 8 above, and in further view of Baidwin et al US 5,238,003.

The combination of Clark and Fischione disclose the claimed invention as discussed above but does not specifically disclose the end piston head has a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose.

However, Baidwin discloses a similar injection pump with an end piston head with a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose (as seen in Fig below), where it allows for passage of air but is impervious to fluids (See Col 4 lines 6-18).



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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Clark and Fischione to include the filter and venting boring and valve hose in view of Baidwan as taught above because it allows for passage of air but is impervious to fluids.

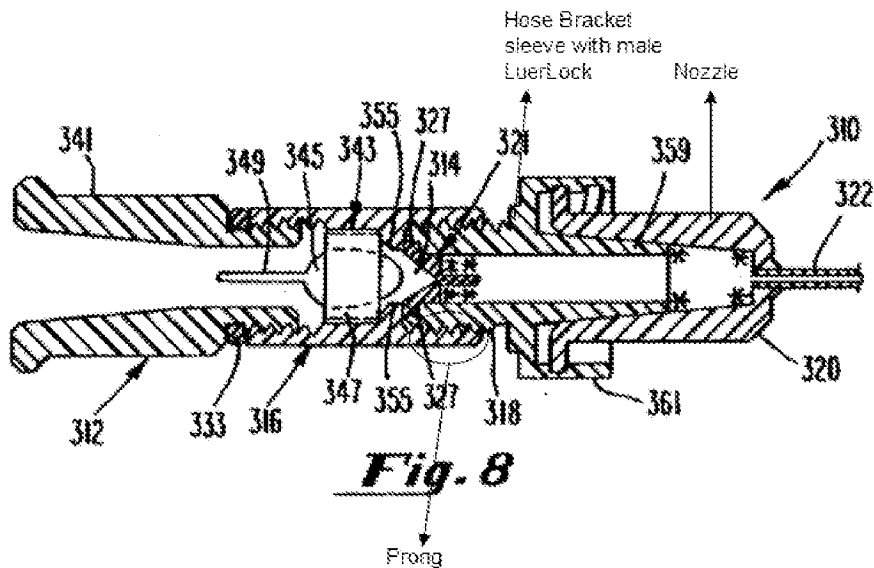
15. **Claims 9-10, 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Shmitz US 3,724,076 and Century US 5,513,630.

Clark discloses the claimed invention as discussed above but does not disclose a hose bracket sleeve with an attached rotatable male LuerLock at the pump body distal end, a nozzle screwed to the rotatable male LuerLock to take up highly viscous media from a respective vessel which nozzle can be unscrewed after absorption of such highly viscous media.

However, Shmitz discloses a similar device where the injection pump (#10) with a bend (as seen in Figs 1-2), a flexible rod (#12) with a Luerlock (#36) for attachment with a nozzle (#30 and see Col 2 lines 54-61) in order to introduce it with filler material (see Col 3 lines 40-60). Century discloses disclose a hose bracket sleeve with an attached rotatable male LuerLock at the distal end of the pump body, wherein a nozzle is screwed to the rotatable male LuerLock to take up highly viscous media from a respective vessel which nozzle can be unscrewed after absorption of such highly viscous media, wherein the male LuerLock is fitted with a prong to fasten the pump body by radially pressure-forcing the pump body into place (see figs below and Col 10 lines 59-65, Col 11 lines 4-24, which teaches a standard male LuerLock to connect with a nozzle, where the LuerLock is attached to the body and is rotatable with prongs that

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help keep the LuerLock in place, which also exerts force on the body).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clark to include the Luerlock and attachment in view of Shmitz because it applies a known technique to a known device ready for improvement to yield predictable results of introducing filler material for displacement. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Clark and Shmitz to include the the rotatable male LuerLock connection and prongs in view of Century because it applies a known technique to a known device ready for improvement to yield predictable results of fastening a nozzle against an injection device through radially pressure-forcing to hole the pump body into place.

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Response to Arguments

16. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733